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Chile

Biotechnology

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Report Highlights:
Events must be registered with Ministry of Health. Government is investing Royalties from copper mining in research and development (up to 2% of GDP) some of which is going to biotechnology.
Mandatory labeling of products containing genetically engineered ingredients is expected to be adopted shortly as Chamber of Deputies voted overwhelmingly to require and Senate is expected to vote on issue before the end of the year.
Currently on products that are substantially different from conventional products must be labeled, genetically engineered seeds may be produced for export under field trials applications from SAG but may not be sold domestically

Includes PSD Changes: No
Includes Trade Matrix: No
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Executive Summary

Chile has a long history of field trials with transgenic seeds. However, to date, no product has been approved for domestic commercialization. All transgenic seeds imported for multiplication must be produced under strict field controls and re-exported. Thus, the general farming community does not benefit from this technology, even though Chilean consumers eat genetically engineered products imported from other countries. The reason for this de facto ban is that Chile is concerned it could lose its Asian and European markets (collectively more than 50 percent of exports) if it openly adopts this technology.

Chile's government recognizes that biotechnology is a crucial tool for a competitive and sustainable economy in Chile, offering varied benefits to producers and consumers. Regarding consumers and biotechnology, labeling is required when foods containing the products of agricultural biotechnology differ substantially from their conventional counterparts.

Although it is unclear how the new Bachelet administration will treat biotech products, her administration appears to be moving cautiously forward along similar lines as the Lagos government.

Work on a draft biotech framework law is continuing, although it appears that the Chilean Congress may decide on mandatory-labeling requirements before the framework law is adopted. This requirement could adversely affect a wide range of domestic and imported processed food products. On June 19th the Chamber of Deputies voted 94-1 in favor of mandatory labeling. The Senate Health Committee currently is debating the issue, the current proposal call for a 1% threshold for biotech content. Also the requirement that all transgenic events used in food must be registered and explicity approved by the Ministry of Health may prove problematic as well. For example, Chile does not grow soybeans. Therefore, there is not commercial incentive for the biotech soybean companies to register their events in Chile. However, many domestic and imported foods contain biotech corn and soybean ingredients.

In terms of commercial interests, Chile could be a consumer of transgenic sugar beets, corn, alfalfa, and soybeans (if the salmon industry were to lift its self-imposed ban on the use of biotech feeds), to name a few crops. Although not widely publicized, Chile has begun to do landmark research in "orphan" crops (non-bulk commodities), such as salmon, pine, stone fruit, apples, and grapes. As part of the government's efforts to increase research and development using funds received from copper mining royalties, Conicyt/FIA/Corfo established 9 consortiums in 2005 of which 6 are doing biotech research.

As with many developing countries, the majority of research funds come from the public sector. However, Chile's biotech university degree programs are still nascent and the link between the public-private sectors on research remains weak. Although an effort has been made to create oversight panels to review the grants being funded, the tech transfer process remains somewhat haphazard. Several government agencies have requested more information on how the U.S. fosters research on commercially viable technologies and aids the transfer of government and academic research to the business community.

However, the agricultural export sector also remains concerned about the trade implications of this technology. They view the issue from the perspective of how will the use of transgenic affect Chile's "natural" image. They argue that currently there are few benefits for the products in which Chile has a competitive advantage (horticultural crops, salmon and

forestry). As Chile is an agricultural export based economy, with agricultural exports accounting for 15% of GDP, these reservations have prompted Chile to take a cautionary approach on biotech issues and play a muted role in international fora such as APEC, MERCOSUR, and OAS, as well as UN and WTO organizations such as FAO, CODEX, and the International Plant Protection Convention (IPPC). Chile signed the Cartagena Protocol on Biosafety, but has not ratified it yet. Nor has Chile established an adventitious presence level for imports yet. However, with a strong regulatory system and a greater investment in the technology, Chile could become an important developing country spokesman in the above-mentioned venues.

Section II. Biotechnology Trade and Production

a) Does Chile commercially produce any biotechnology crops? Chile does not produce any crops for sale domestically. However, Chile has produced transgenic seeds under strict field controls for re-export for more than a decade. See Section VI. Reference Materials, Appendix A. Table of Approved Biotechnology Products.

b) Are there any biotechnology crops under development in your country that will be on the market in the coming year? Appendix A shows the field trials and seeds being propagated in Chile. Additional research is being conducted on such crops as citrus, stone fruits, grape vines, pine, and salmon. However, none of these crops are scheduled for commercial release domestically within the next year.

c) Does the country import biotechnology crops/products? Yes. See Appendix A. Of the 140 field trial requests, 115 were from the United States. The main crops are corn, soybeans, canola, tomatoes, squash, sugar beets, and safflower seeds. Chile also imports processed food products containing transgenic ingredients from many countries including Canada, the US, Brazil, Mexico, Argentina, and the European Union.

d) Is Chile a food aid recipient or likely to be a food aid recipient in the near future? No

e) Does Chile produce any biotechnology crops that were developed outside of the United States and have not passed through the US regulatory system? Crops from other countries have been approved for field trials in Chile, however the events have been approved in the United States as well.

Section III

a) . Responsible Government Ministries and their role.

See the list in Section VI for the contact information for each office:

- The Agricultural Livestock Service (SAG), Ministry of Agriculture is responsible for analyzing applications to conduct field trials or grow and market transgenics. Through both a document review process and consultations with technical experts (CALT-Advisory Council on the Release of Transgenics), SAG performs the environmental risk assessment. The application includes a complete description of the botanical, agro economic, and molecular aspects of the different components of the new cultivars, including studies evaluating possible environmental interactions and methods of controlling possible gene flow.

- The Ministry of Health sets the rules governing food safety, including labeling requirements and approves ingredients for human consumption. In January 2000, the food law was modified to require a case-by-case analysis to authorize transgenic products for human consumption. However in November 2004, a derogation was introduced while the Ministry of Health reviewed its mechanisms for implementing this requirement. Currently mandatory labeling of transgenic foods/ingredients is required when the product is substantially different from the conventional product.

- The Regional Ministry of Health offices (SEREMIS SALUD) provides import approvals for foods, based on the regulations established by the Ministry of Health. Currently there is no official adventitious presence level. However, if/when the Ministry of Health implements its proposal to require events to be registered or Congress adopts a new labeling requirement, the Regional Offices will be responsible for enforcement.

- CONAMA (Environmental Commission) represents Chile at the Biosafety Protocol meetings, participates in the National Biotechnology Commission, and is on the National Committee on Biosecurity Matters. However, they are not specifically authorized under the current regulatory structure to do environmental impact assessments for transgenic products.

- The Agricultural Research Institute (INIA), creates, adapts and transfers scientific know-how and technology to the agricultural community via its centers, libraries, and laboratories. Currently, they are the lead government agency in the area of practical research in biotech crops in Chile.

- The National Commission for Technology and Scientific Research (CONICYT) defines science and technology policy; promotes and finances science and technology research programs and projects; promotes international cooperation and increases public awareness and understanding of the benefits that accrue to the country as a result of its investment in scientific and technological research.

- The Foundation for Agricultural Innovation (FIA) is part of the Ministry of Agriculture and finances programs that incorporate innovative production processes or creative industrial or marketing methods in agriculture, livestock, forestry, and aquaculture. They have funded projects and training in the area of biotechnology.

ii. Role and membership of Biosafety Committee (if any).

Chile signed the Cartagena Protocol on Biosafety, but has not ratified it yet. On November 30, 2000, a National Committee for Biosecurity Matters was established. CONAMA is on this committee and has represented Chile at the international Biosafety Committee meetings. In general, though, Chile has not taken any lead positions in international venues pending adoption of its national biotechnology framework law.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology.

Chile is an agricultural export based economy, with agricultural exports accounting for 15% of GDP. The agricultural export sector has voiced some concerns about the trade implications of this technology. They view the issue from the perspective of how will the use of transgenics affect Chile's "natural" image. They argue that currently there are few benefits for the products in which Chile has a competitive advantage (horticultural crops, salmon and forestry). These reservations have prompted Chile to take a cautionary approach on biotech issues and play a muted role in international fora such as APEC, MERCOSUR, and OAS, as

well as UN and WTO organizations such as FAO, CODEX, and the International Plant Protection Convention (IPPC).

In an attempt to address some of the concerns being voiced by special interest groups, President Ricardo Lagos established a National Biotechnology Commission to review all aspects of this technology. The Commission made several recommendations, including proposing that a framework law be developed to govern trade, research, marketing and regulation of biotech products. The Lagos Administration has prepared a draft bill for Congress, but it was never submitted because of the Presidential elections in December 2005, it is uncertain whether this bill will be submitted this year under the new Bachelet Administration.

On June 19, 2006 the Chamber of deputies voted almost unanimously to adopt mandatory labeling. The detection threshold for biotech content is 1% and should be label as "Genetically Modified Product". The bill is now with the Senate Health Committee. Finally, select NGOs have called for GMO free zones in the country. This was deemed unconstitutional. However, a few Congressmen in response to these special interest groups are researching how voluntary zones might be created.

b) List biotechnology crops that have been approved for:

i. Food, processing, and feed – none

ii. Environment – See Appendix A, which shows crops approved solely for multiplication and re-export.

c) Does Chile allow field-testing of biotechnology crops? Yes, currently strictly for re-export.

d) Please note the treatment of stacked events.

If all the genes have been approved individually by SAG they go through an expedited process. They still have to be approved as a new event, but the process is simplified.
If the genes have not been approved individually or one of them has not yet been approved, the stacked event is considered to be a whole new event, and it must go through a full review.

e) What is Chile's policy on coexistence between biotechnology and non-biotechnology crops? Are there rules in place or proposed on coexistence?

There currently are no specific rules on the subject of coexistence, but Resolution 1523 of 2001 introduced a traceability system and documentation requirements for all seeds and the fields where they are planted. As part of the process for every field trial approval, biosafety measures are established, such as physical isolation from sexually compatible species and post harvest management. The draft framework bill is expected to specifically address this issue, but is unclear what modification may be made to this document under the new Bachelet Administration. She is not opposed to biotechnology, and many of her ministers are openly proponents of the technology, however, she has not taken a public stance on the issue to date. The Ministry of Agriculture has hosted several open forums on this topic, with panelists ranging from agronomists, economists, regulators, activists and trade and legal experts. The question of liability has been openly vetted in these meetings, although the final draft language is not available yet.

f) Does the country require labeling for packaged foods or feeds?

For human consumption, mandatory labeling currently is required for products and/or ingredients that are substantially different from their conventional counterparts. There are no labeling requirements for crops, as currently there are no crops approved for domestic commercialization. Even without the Ministry of Health regulation for registering events, the Chilean Chamber of Deputies voted almost unanimously 2006 a project of law to label all food product containing genetically engineer ingredients. The project is now under consideration by the Health Commission of the Senate. The proposal calls for a 1% threshold for biotech content over which products would have to bear the language "Genetically Modified Food" on the label.

g) Has Chile signed or ratified the Biosafety Protocol?

Yes, but they have not ratified it yet. Given this is a presidential election year, and there are many other issues of greater domestic interest to be addressed by the current administration, it is unlikely it will be ratified in the near future.

h) Biotechnology-related trade barriers.

Currently there is a Ministry of Health requirement that all transgenic events be reviewed by the Ministry of Health, registered and explicitly approved prior to allowing their use in domestic and imported foods. This could prove problematic in situations where the crop is not grown domestically. For example, Chile does not grow soybeans. Therefore, there is no market for soybean seeds. Thus, there is little incentive for the seed company to apply to register the event. Yet, without the event being specifically approved by the Ministry of Health, many imported processed foods could encounter problems in the future.

In terms of commercial interests, Chile could be a significant consumer of transgenic soybeans, but the salmon industry has chosen to impose a de facto ban on the use of biotech feeds, due to their concerns that European and Japanese consumers might reject the product. While these types of industry imposed constraints clearly adversely affect trade, they are not formal technical barriers to trade.

i) Is there pending legislation with the potential to affect exports?

As previously mentioned, there is a mandatory labeling proposal approved by the Chamber of Deputies is currently being debated by the Senate Health Committee. If adopted with a 1% threshold detection level for biotech ingredients many domestic and international products could be affected.

j) Are there 'technology fees' for commercially planted crops? No

Section VI. Marketing Issues

a) Market acceptance issues for producers, importers, retailers and consumers.

Currently there are no high visibility advocates of this technology. The scientific/academic community and parts of the agricultural community (corn and sugar beet farmers) are proponents of allowing genetically engineered products to be marketed domestically, but have not been very vocal in their support. At the same time, Chile's traditional export sectors (wine, salmon, and fresh fruits) remain concerned about the effect adoption of this technology might have on their markets in Europe and Japan. These sectors are doing research in genome mapping and, in the case of the salmon industry, research in transgenic

vaccinations, but they also have distanced themselves from being perceived as in favor of genetically engineered products. Consumer understanding of the issue is uninformed, with exposure mainly being to alarming reports from special interest groups. Neither importers nor retailers have taken a stance on the issue.

b) Relevant studies on the marketing of biotechnology products.

INIA has a series of relevant publications and books that can be purchase from their library. You can find a list at the following website: http://www.inia.cl/biotecnologia/

The following website shows a diagnosis of the biotech industry applied to forestry, food and horticultural products.
http://www.prospectivatecnologica.cl/inicio/documento.php?id_avance=104

This site shows a study on biotechnology applied to the forestry industry
http://www.prospectivatecnologica.cl/inicio/documento.php?id_avance=115

Bioplanet, contains extensive information on national and international biotech developments.
http://www.bioplanet.net/index.htm

Fundación Chile, a non-governmental research organization, conducts biotech studies.
http://www.fundacionchile.cl

Explora, disseminates information and S&T developments:

The following web site includes a paper from the 10th National Week of Science and Technology called "Biotechnology, Yesterday, Today and Tomorrow".
http://www.explora.cl/exec/cyt/experimento/ficha.e3?id=43

This sites has information on "Biotechnology, Science and Technology for Humankind"
http://www.explora.cl/exec/cyt/experimento/ficha.e3?id=41

This site has information on "National System of Information on Biotechnology"
http://www.biotecnologia.gob.cl/

This site has Biotechnology information for the Chilean industry
http://www.sofofa.cl/sofofa/index.aspx?channel=3732

Biotechnology as a tool for development and well-being
http://www.acti.cl/publicaciones/biotecnologia.htm

Section V. Capacity Building and Outreach

a) U.S. Government or USDA funded capacity building or outreach activities.

Past biotechnology activities in Chile include: Embassy Science Fellowship program with the participation of a USDA/ARS scientist for two months in Chile from May-July 2006. Ministry of Agriculture Official was sent to a training course in the Philippines in June 2006 on Commercializing biotech crops. The U.S. Government participated on the APEC HLPDAB hosted by Chile in November 2005, we organized a reverse CODEL to the U.S. to be learn about the U.S. regulatory System for Biotech products in July 2005; We sponsored a Chilean expert to

attend the APEC Seminar: "Creating a Positive Investment Environment for Agricultural Biotechnology", in Malaysia in Dec 04; we organized a panel of experts to address the Chilean Agriculture and Health Committees in Oct 04; we sent the President of the Small Farmers Cooperative Confederation to a farmer-to-farmer training program in Honduras in Aug-Sept 04; we sponsored two participants to attend the Michigan State biotechnology short course in August 2004; we hosted a visit to the U.S. of a team of Ministry of Health officials tasked with gathering information about other countries biotech regulations in Mar-Apr 04; we coordinated between the Einstein Institute for Science, Health and the Courts (EINSHAC) and the Chilean Judicial Institute to provide technical training to the judiciary regarding biotechnology in civil, criminal and family cases in Mar 04; we organized the HLPDAB in Chile, in Feb 04 and funded the participation of 22 representatives from APEC emerging markets to attend, as well as nine speakers.

b) Country specific needs or strategies for Chile.

The objective of the above-mentioned activities was to promote science based regulation for biotech foods, especially in the case of food labeling, and to generate Chilean support in international standard setting bodies for reasonable requirements. The programs also were intended to build long-term regulatory acceptance for future biotech food crops using science bases principals to conduct risk assessments and to foster the adoption of common documentation for trade in bulk commodities under the Biosafety Protocol.

Also an effort was made to facilitate/refine/build mechanisms for enhancing public/private collaboration in biotechnology. Work in this area should continue. By improving the communication between the Chilean agricultural export community and the R&D facilities and by streamlining the tech transfer process within Chile, the development and adoption of biotech crops of economic interest to Chile could be increased and consequently so probably would be Chile's participation in the international dialogue on how biotech crops are handled globally.

Finally, and probably the most important focus should be on educating the public and Congress. Activities targeting journalist, Congress and general public through the schools could help form the debate on labeling and general acceptance of genetically engineered products. Specially, a train the trainer workshop would be helpful to help the regulators educate and inform the public about biotechnology. Finally, the Ministry of Health and the Public Health Institute have requested technical training for their laboratory officials. They received a grant from the European Union to build a lab and need technical information on how the U.S. uses its laboratories to comply with its international commitments.

Section VI. Reference Materials

Contact Information for Government Agencies:

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